WHITE PAPER

Clinical Supply Strategies to avoid Overages & Stock Outs

70% of the issues encountered in IRT are around Clinical Supplies, the consequences could be disastrous to merest. Advanced supplies settings coupled with inputs from forecasting tools should be capable of avoiding overages and stock outs at depot and sites.

Causes for Supplies Issues

Huge number of subjects, more sites, large number of countries, increase in the number of users, ancillary supplies, sharing of supplies among protocols, sensitive medication, adaptive studies, titration studies, regulatory rules around controlled substances, introduction of shipper/box, manufacturing, packing, labeling, challenges in physical shipping, wrong location of physical depots, unrealistic estimates, dose differences.

Consequences of Supplies Issues

Monetary losses, loss of subjects, missing visits, incomplete data, etc.

Medication Needs at a Site

All the effort we put around clinical supplies boils down to satisfying medication needs at a site and it can be classified into two.

Non Predictable Needs

This type of Kit needs cannot be predicated – New subjects, Lost Kits, Damage Kits, Quarantine Kits and Unscheduled Visits

Predictable Needs

This type of Kit needs can be predicted – Scheduled Visits. Randomization falls in between Non Predictable and Predictable needs

Supplies Strategies to Satisfy Needs at Site

An IRT system should be capable of handling Site Needs through automatic shipment settings backed up by manual shipment functionality. Design to send blinded and unblinded Shipments.

- **Buffer Strategy:** Handles non predictable needs
- **Prediction Strategy:** Handles predictable needs

Randomization needs can be either satisfied though Buffer Strategy or Predication Strategy by configuration.

Initial shipment sent to the site should be capable of triggering on site activation or first subject screened for the site based on the requirement.

Inventory Release/update

Inventory is released into Central depot associating with a specific country, lot number and expiry date which is completely editable at any point of time. Able to including Kits from multiple lots into a Shipment. Expiry date to be editable at lot and sequence range levels.

An IRT system should be capable of fully handling Discrete (Kits with kit numbers) and Bulk (Kits without kit numbers) Kits.

Changing Kit Status

Status of the Kits can be changed among Available, Quarantined, Damaged and Lost at Site and Depots level.

Supply Parameters

Do Not Dispense

Ensures the Kits that are given to Subject are not expired during Treatment Period

Do Not Ship

Ensures Kits shipped from Depot to Site are not hitting DND during shipping, Treatment Period and some period of time

Do Not Consider

Ensures Kits at Site that are hitting DND during a shipment from depot to site, during Treatment Period and for some certain time period are replaced

Parameters setting at various levels

With the flexibility of having parameters set up at Study, Country and Site levels allows supplies to flow in precise and accurate quantity and timelines.

As DNS and DNC based on Lead Time and Lead Time varies mostly based on a country. Country level settings for DNS and DNC backed up Study and Site level setting is user friendly and accurate.

Supplies Demand

Can apply different settings at Study, Country and Site Levels for Buffer Strategy, Predication Strategy and Initial shipments is the most user friendly way to handle supplies for studies with huge number of sites, countries with variability.

Tracking of Supplies

Tracking of supplies at shipment and kit levels throughout the flow based on location and status is must for a modern IRT. Robust reporting and alerting system is the base to avoid fire fighting and issues.

An IRT system should be Flexible, Quick, User-friendly, Accurate, Reliable, and Esthetic backed up by experienced Technical and Subject Matter Expert Teams

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